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(54) Title: A DRESSING			
(57) Abstract			
<p>A dressing for covering a portion of the anatomical surface of a living being, said dressing being able to adhere to the skin, the mucosa and/or a wound on a portion of a living being, said dressing comprising a substantially water-impervious layer and a skin-friendly adhesive, said water-impervious layer has a pattern of indentation characterised in that the gap of the indentations in the water-impervious layer is diminishing or disappearing when the dressing is moistened.</p>			

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TITLE

A dressing

FIELD OF THE INVENTION

The present invention relates to dressings, in particular dressings for covering a portion of the anatomical surface of a living being and a method of preparing such dressings.

BACKGROUND OF THE INVENTION

Conventionally, dressings for the treatment or prevention of wounds or pressure sores are essentially flat dressings with a substantially smooth surface. They 10 comprise a backing layer, being covered on one side with a skin-friendly adhesive, optionally containing dispersed particles of hydrocolloid.

When a dressing is applied to an exuding wound the hydrocolloid will begin to absorb the wound exudate. When absorbing moisture, the hydrocolloid will swell and at the dressing will obtain a slightly more pale colour. The swollen hydrocolloid will create a humid climate over the wound which may promote the healing of the wound. However, if the dressing is left on the wound for too long, the dressing 15 will absorb so much moisture that not only the part of the dressing immediately over the wound is humid but also the area over the healthy skin surrounding the wound. Contrary to the wound, this healthy skin will suffer from the contact with the moist hydrocolloid and may be damaged, e.g. by maceration.

Accordingly, a critical consideration in wound care is the frequency of changing of dressing. It may be desirable to change dressings frequently when the wound is producing large volumes of exudate, and less frequently when the wound is producing less exudate. Nevertheless, each time the dressing is changed there is 25 a risk that the sensitive tissue such as granulation tissue and epithelial tissue will be unnecessarily damaged. Additionally, positive growth factors in the wound fluid might be unnecessarily removed from the wound bed, thereby preventing

their positive effects. Therefore, it is important to change the dressing when appropriate but not too often.

The usual way of detecting when it is time for changing the dressing is by visual inspection and determining the extension of the swollen area of hydrocolloid by 5 looking at the colour of the dressing, as the hydrocolloid dressing is turning pale when absorbing moisture. It is also known to incorporate colour indicators showing with a colour change when the dressing is moistened.

When the hydrocolloids absorb water they will also swell and expand rendering it possible to feelably detect the condition of the dressing, from an increased thickness. However, it is often difficult to feel the border line between the swollen and 10 the non-swollen hydrocolloid as it is not distinct but diffuse.

In US Patent No. 3,675,654 is disclosed a disposable article such as a diaper, sanitary napkin or a bandage providing a visual indication of wetness. The article comprises an absorbing pad disposed on a translucent backing layer, and a 15 moisture-actuated indicating agent there between. When wetted, the indicating agent will present a change of colour, being visible through the translucent backing layer of the article.

WO publication No. 98/12996 discloses a wound dressing with a visual indicator of changing. The backing layer of the dressing is bearing a reference marking, 20 and when the swelling of the hydrocolloid extends to or beyond the reference marking, the dressing should be changed.

These references are only showing visual indications of dressing change, and suffers further from the drawback that the backing layer has to be of a translucent composition. .

Dressings with different kinds of colour indicators are known, e.g. from European Patent application No. 430 680, which discloses a wound dressing comprising a temperature sensing liquid crystal tape, affixed to the backing layer.

It is also known to provide wound dressings with indentations for increasing the
5 flexibility of the dressing, or for ornamental use only.

WO publication No. 92/05755 discloses a wound dressing of the hydrocolloid type which includes a peripheral flange of reduced thickness along the edge of the dressing. The reduced thickness of the flange provides a tighter fit to the skin. The central part of the dressing is of uniform thickness.

10 In European Patent application No. 768 071 is disclosed a dressing especially for sacral wounds which the dressing is made more flexible for application to contoured parts of the body by making indented lines or grooves in the dressing, particularly along the central axis of the dressing. These indentations makes it easier to bend the dressing into the desired conformation in order to contact the
15 wound.

From BE Patent No. 09500989 is known an adhesive dressing comprising a relief-pattern. This pattern has only ornamental purpose, and does not influence on the physical properties of the dressing.

Surprisingly, it has been found that by introducing a pattern of indentations on the
20 dressing a both visible and feelable indicator may be obtained, as the indentations may diminish or simply disappear when the dressing absorbs moisture. The determination will not be dependent on the translucency of the backing layer.

BRIEF DESCRIPTION OF THE INVENTION

The invention relates to a dressing for covering a portion of the anatomical
25 surface of a living being, said dressing being able to adhere to the skin, the mucosa and/or a wound on a portion of a living being, said dressing comprising a

substantially water-impervious layer and a skin-friendly adhesive, said water-impervious layer has a pattern of indentation.

The invention also relates to a method for preparing a dressing for covering a portion of the anatomical surface of a living being, said dressing being able to
5 adhere to the skin, the mucosa and/or a wound on a portion of a living being said dressing comprising a substantially water-impervious layer or film and a skin-friendly adhesive wherein the water-impervious layer or film has a pattern of indentation.

Furthermore, the invention relates to a dressing for covering a portion of the
10 anatomical surface of a living being, said dressing being able to adhere to the skin, the mucosa and/or a wound on any portion of a living being, said dressing comprises a temperature-sensitive colour.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is explained more in detail with reference to the drawings in which:

- 15 Figure 1 shows a cross-section of an embodiment of the invention.
Figure 2 shows the embodiment of Figure 1 when moistened.
Figure 3 shows a top view of another embodiment of the invention.
Figure 4 shows a top view of a third embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

- 20 The present invention relates to a dressing for covering a portion of the anatomical surface of a living being, said dressing being able to adhere to the skin, the mucosa and/or a wound on a portion of a living being, said dressing comprising a substantially water-impervious layer and a skin-friendly adhesive, said water-impervious layer has a pattern of indentation, said dressing being characterised
25 in that the gap of the indentations in the water-impervious layer diminishing or disappearing when the dressing is moistened. The dressing is optionally covered in part or fully by one or more release liners or cover layers to be removed before or during application.

The pattern of indentations can be a geometric pattern, for example raised or retracted dots, cubes, pinpoints, lines, ribs, or waves, systematic as well as randomised. Alternatively it can be letters, figures, pictures as for example a cartoon. The indented grooves of the pattern will, when the hydrocolloid of the

5 dressing absorbs moisture and swells, diminish or simply disappear. The pattern covers preferably at least a part of the dressing, more preferred the central part of the dressing. The pattern is preferably designed so as to disappear after the dressing has absorbed the intended amount of moisture between two placements of the dressing so as to indicate the time of exchange in a simple manner.

- 10 In a preferred embodiment, the pattern only covers the wound covering part of the dressing.

The deeper the indentations, the more distinct is the pattern of the dressing. The depth of at least some of the grooves is preferably at least 25 % of the thickness of the dressing, more preferred at least 50 % of the thickness of the dressing.

- 15 It is also considered an aspect of the invention to provide a dressing with indentations of two or more depths for enabling a stepwise indication of the remaining time service according to the invention. Such effect may also be obtained by providing the dressing with indentations having increasingly depth over the length thereof.

- 20 The indented pattern is suitably in the form of dots, pinpoints, cubes or lines.

Apart from providing an indicator to the dressing, the indented pattern may also increase the flexibility and the wearing comfort the dressing. While increasing the surface of the dressing by making indentations, the contact surface of the dressing decreases, which causes e.g. a sleeve or a sock to slide more easily on the

25 dressing.

To support the visual effect of the pattern, the dressing can be coloured, either in a single colour or in a pattern of more colours. This colour pattern can for example interact with the indented pattern in a decorative or functional way.

When the dressing is applied to a persons skin, the dressing will begin absorption
5 of exudate from the wound. The dressing will swell as it absorbs the exudate and the swelling causes the pattern to diminish or disappear. This effect may serve as an indicator for when to change the dressing, as stated above, and the indication will be both visible and physically or manually detectable. To enhance the visual indication, an indicator of wound exudate or moisture can be incorporated in the
10 dressing, showing a change of colour when the dressing is due for exchange.

Before applying a hydrocolloid dressing it is often recommended to heat the dressing in the hands for a few minutes to increase the adhesive force and tack of the dressing. In a preferred embodiment a temperature-sensitive colour is incorporated in the dressing, said colour having a sensitivity point close to the
15 optimal temperature of the dressing to be applied. The dressing will then show one colour when cold and change to another colour when sufficiently heated. In this way the user has a good indication of the right time to apply the dressing. Both reversible and non-reversible colour indicators can be used. A temperature-sensitive colour can be arranged in a functional or decorative pattern on the
20 dressing, e.g. as the letters "ready" show up when the dressing is sufficiently heated.

The shift of temperature is preferably in the range from 15°C to 50°C, more preferred in the range from 15°C to 35°C.

The temperature-sensitive colour can be of the liquid crystal type, for example
25 lanthanoid-compounds.

Another embodiment comprises a dressing with a colour indicator, which colour indicator can be triggered by different factors. Examples are colours sensitive to

light (one colour in sunshine - another in rain), humidity/moisture, temperature or pressure (change of colour when pressure is applied). These colour reactions can be both reversible and irreversible. The colour change of the dressing can be a great entertainment for the user, especially children, and thereby distract his

5 attention from the wound.

In accordance with a preferred embodiment of the invention the dressing is provided with one or more indications giving irreversible change on external stresses or actions and thus serving as a recording of the affects influencing the wound site.

- 10 The water impervious layer may be of any suitable material known per se for use in the preparation of wound dressings e.g. a foam, a nonwoven or a polyurethane, polyethylene, polyester or polyamide film.

A suitable material for use as a water impervious film is a polyurethane. A preferred low friction film material is disclosed in US Patent No. 5,643,187.

- 15 A dressing to be provided with indentations according to the invention may be prepared by a manner known per se for the preparation of medical dressings by substituting the raw materials and it will be routine for the skilled in the art to adapt the process parameters to the actual materials.

- The dressing of the invention preferably has bevelled or contoured edges having
20 reduced thickness as compared to the main part of the dressing in order to reduce the risk of "rolling-up" the edge of the dressing, as well as the pattern can be made by bevelling. A bevelling or contouring may be carried out discontinuously or continuously in a manner known per se e.g. as disclosed in EP patent No. 0 264 299 or in US patent No. 5,133,821.

- 25 A protective cover or release liner may for instance be siliconised paper. It does not need to have the same contour as the dressing, e.g. a number of dressings

may be attached to a larger sheet of protective cover. The protective cover is not present during the use of the dressing of the invention and is therefore not an essential part of the invention.

- Furthermore, the dressing of the invention may comprise a "non touch" grip
- 5 known per se for applying the dressing to the skin without touching the adhesive layer. Such a non-touch grip is not present after application of the dressing.

The invention also relates to a method of preparing a dressing for covering a portion of the anatomical surface of a living being, said dressing being able to adhere to the skin, the mucosa and/or a wound on a portion of a living being said

10 dressing comprising a substantially water-impervious layer or film and a skin-friendly adhesive wherein the water-impervious layer or film has a pattern of indentation, characterised in that the pattern of indentation is pressed into the film after combination of the film and the skin-friendly adhesive. The dimension of the pattern is preferably chosen so as to ensure that the indentations disappear after

15 the dressing has absorbed the amount of moisture corresponding to the capacity indicating a replacement. The dimensions of the indentations may be determined by routine experiments.

The indentations preferably reaches into the layer of adhesive too and preferably does not break the film.

- 20 The indentations may preferably be made using rollers having a corresponding surface pressing the dressing. Indentations may be prepared before, concomitantly with the cutting of the individual dressings or even after.

Instead of indentations, the dressing of the invention may show a relief in the form of ridges or bulges. Thus, a relatively thin and flexible product having a high

25 capacity of absorption may be obtained.

In a further aspect the invention relates to a dressing for covering a portion of the anatomical surface of a living being, said dressing being able to adhere to the skin, the mucosa and/or a wound on a portion of a living being, said dressing comprising a substantially water-impervious layer and a skin-friendly adhesive in 5 which one or more colours which will change colours upon change of the level of moisture or temperature are incorporated in or printed on the dressing.

The skin-friendly adhesive may be any skin-friendly adhesive known per se, e.g. an adhesive comprising hydrocolloids or other moisture absorbing constituents for prolonging the time of use. The adhesive may suitably be of the type disclosed 10 in those disclosed in GB patent specification No. 1 280 631, in DK patent specifications Nos. 127,578, 148,408, 154,806, 147,226 and 154,747, in EP published application Nos. 0 097 846 and 0 415 183, in SE published application No. 365,410, in WO publication No. 88/06894, in US patent specification No. 4,867,748, and in NO published application No. 157,686. Especially preferred are 15 the adhesives disclosed in US patent Nos. 4,367,732 and 5,051,259 and DK patent specification No. 169,711.

DETAILED DESCRIPTION OF THE DRAWINGS

The invention is explained more in detail with reference to the drawings showing embodiments of the invention. Reference is made to Figure 1 showing a cross-20 section of a dressing (1) with a indented pattern with raised points (2) and grooves (3). The dressing comprises a water-impervious layer (5) and an adhesive layer (6). The edge (4) is bevelled.

Figure 2 is showing the same embodiment of the invention as in Figure 1, after the dressing has been applied to an exuding wound. The central part of the 25 dressing has absorbed moisture from the wound and is swollen giving rise to the grooves or gaps of the indentations to diminish (7) or disappear (8).

Figure 3 shows a top view of another embodiment of a dressing according to the invention. This embodiment shows a pattern in the form of cassette-like areas (2),

grooves (3) and a bevelled edge (4). The pattern may also be "reverse", i.e. the indentations are in the form of indentations (2) separated by ridges (3).

In Figure 4 is shown a third embodiment, where the dressing (1) is shaped as an essentially circular central part with flaps on the two opposite sides. The indented pattern is made in a form with ribs in waves, like a washboard, this pattern offers a good flexibility in both directions.

CLAIMS

1. A dressing for covering a portion of the anatomical surface of a living being, said dressing being able to adhere to the skin, the mucosa and/or a wound on a portion of a living being, said dressing comprising a substantially water-
5 impervious layer and a skin-friendly adhesive, said water-impervious layer has a pattern of indentation characterised in that the gap of the indentations in the water-impervious layer is diminishing or disappearing when the dressing is moistened.
2. A dressing according to claim 1 characterised in that the indented pattern is in
10 the form of dots, pinpoints, cubes or lines.
3. A dressing according to claim 1 or 2 characterised in that at least some of the indented grooves are at least half the thickness of the dressing.
4. A dressing as claimed in any of claims 1-3 characterised in that one or more colours are incorporated in or printed on the dressing.
- 15 5. A dressing according to claim 4 characterised in that the colour is temperature-sensitive.
6. A dressing as claimed in any of claims 1-5, characterised in that the substantially water-impervious film is of polyurethane.
7. A method of preparing a dressing for covering a portion of the anatomical
20 surface of a living being, said dressing being able to adhere to the skin, the mucosa and/or a wound on a portion of a living being said dressing comprising a substantially water-impervious layer or film and a skin-friendly adhesive wherein the water-impervious layer or film has a pattern of indentation, characterised in that the pattern of indentation is pressed into the film after combination of the film
25 and the skin-friendly adhesive.

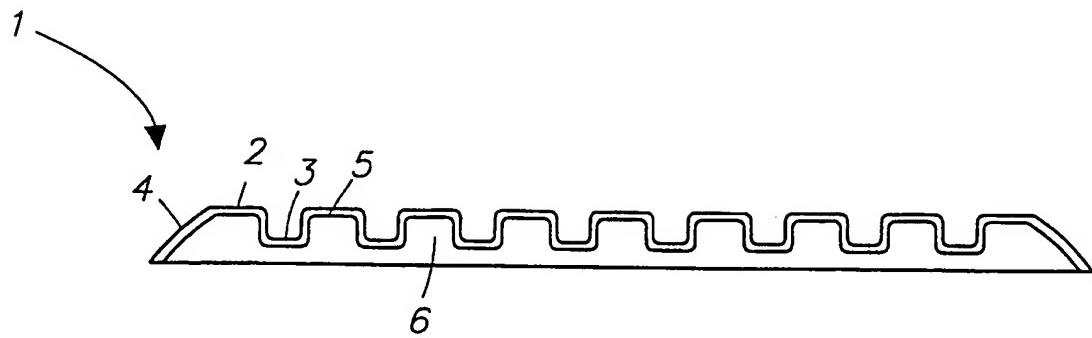


Fig. 1

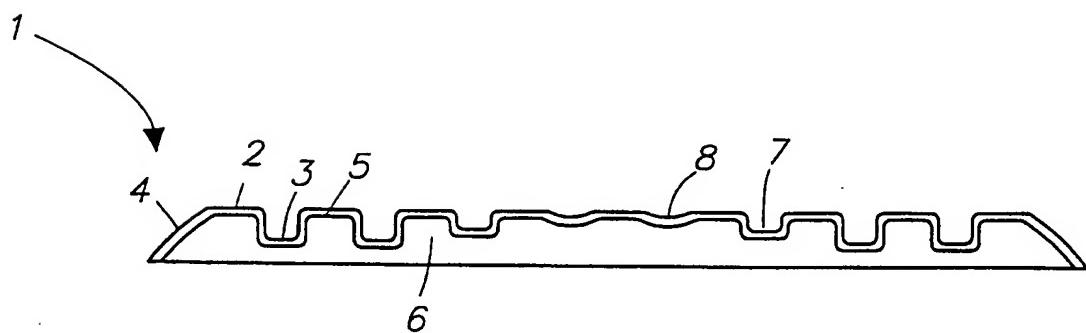


Fig. 2

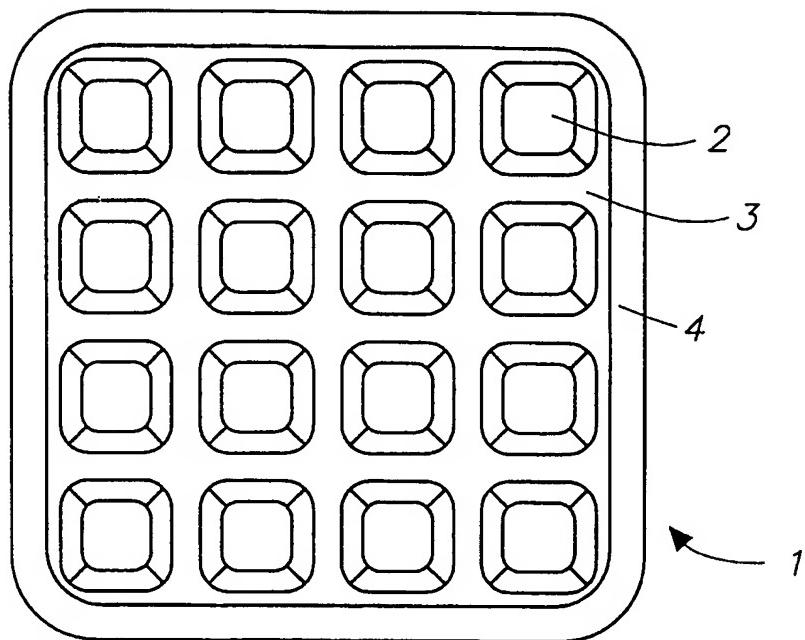


Fig. 3

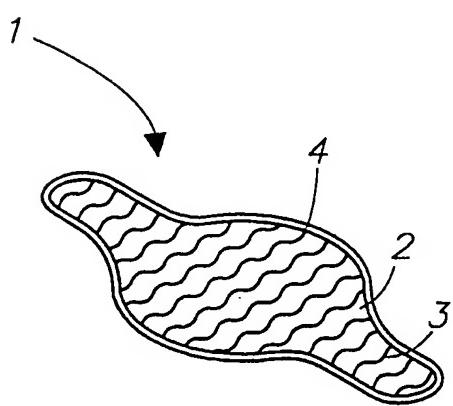


Fig. 4

1
INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 99/00024

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 13/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0768071 A1 (JENSEN, OLE ROGER), 16 April 1997 (16.04.97), column 2, line 20 - line 36; column 4, line 32 - line 34, figure 3	1-3,6
Y	--	4,5
X	WO 9300056 A1 (COLOPLAST A/S), 7 January 1993 (07.01.93), page 3, line 10 - line 16, figures 2,3, abstract	1-3,6
Y	--	4,5
X	US 5112618 A (CARTMELL ET AL), 12 May 1992 (12.05.92), column 3, line 63 - line 68	7
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Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:	
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INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 99/00024

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5181905 A (FLAM), 26 January 1993 (26.01.93), column 3, line 8 - line 10 -- -----	4,5

INTERNATIONAL SEARCH REPORT

Information on patent family members

03/05/99

International application No.

PCT/DK 99/00024

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
EP 0768071 A1	16/04/97	US 5704905 A		06/01/98
WO 9300056 A1	07/01/93	DE 69213014 D,T EP 0591440 A,B JP 6508775 T US 5486158 A		23/01/97 13/04/94 06/10/94 23/01/96
US 5112618 A	12/05/92	AT 114975 T AU 627942 B AU 6491190 A CA 2028528 A DE 69014835 D,T DK 426422 T EP 0426422 A,B SE 0426422 T3 ES 2064662 T JP 3207357 A JP 8024695 B US 5059424 A		15/12/94 03/09/92 09/05/91 02/05/91 04/05/95 13/02/95 08/05/91 01/02/95 10/09/91 13/03/96 22/10/91
US 5181905 A	26/01/93	AU 647421 B AU 6573590 A CA 2029172 A DE 69016950 D,T EP 0430608 A,B JP 3182246 A		24/03/94 06/06/91 29/05/91 14/06/95 05/06/91 08/08/91